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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,410	04/12/2001	Toyohiro Sawada	019941-000510US	3651

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,410	SAWADA ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8 and 10-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8 and 10-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Response/Amendment filed 02/24/04.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 3-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "to a certain extent" in claim 1 is a relative term, which renders the claim indefinite. The term "to a certain extent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. The term can be different things to different observers and is a completely subjective description of an object based off of personal opinions and no objective unit of measure. What is within the certain extent for one person is not for another. Therefore claim 1 is rendered indefinite, along with all subsequent claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 3-8, and 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Dandiker et al (USPN 5,425,950), Nakishima et al (EP 0 661 045), Taniguchi et al (EP 0 709 386), Wong et al (USPN 5391,381) and Kawata et al (USPN 4,404,183). The claims are drawn to a compressed-coated tablet. The tablet's core comprises fillers and an active agent. The outer layers comprise a hydrogel-forming polymer. The active agent is recited as CYP3A4. The fillers are well known in the art (sucrose, lactulose, polyethylene glycol, etc.). The hydrogel forming polymers are equally well known in the art.

1. Dandiker et al teaches a compressed coated tablet where the core comprises fillers, which can erode, along with active agents (col. 6, lin. 15 – 24). Sucrose starch, and other common erodible fillers are listed (col. 5, lin. 48 – 50). The outer layer comprises hydrogel-forming polymers (examples). The reference does not disclose that the filler erodes 40-90%, yet the claims do not state a time frame for this erosion. Any known filler will erode 40-90% in the digestive tract given enough time. No indication is given in the claims or throughout the specification that the filler has been modified in anyway as to render it only erodible to this percentage. It can be concluded that any filler would erode tot his percentage given enough time in the digestive tract. Barring an inclusion of a time frame or dissolution profile, the limitation to the percentage of erosion of the filler, cannot be given patentable weight.

Nakashima discloses a compression-molded tablet comprising a hydrogel-forming polymer and a hydrophilic base. The tablet of Nakashima also contains a drug. The disclosure recites various drugs ranging from anti-inflammatory agents to central nervous system drugs

such as idebenone. Also the tablet is formulated to release or be absorbed in the lower digestive system (pg. 3, lin. 25 – 35). Polyethylene glycol and polyethylene oxide are used as the hydrophilic base/hydrogel-forming polymer used in the tablet of Nakashima (Examples). The outer coating has viscosity and molecular weight specification, which meet those of applicant's claims.

Taniguchi discloses a fused benzazepine derivative, which can be useful as a vasopressin antagonist. The drug can be formulated into tablets using conventional excipients such as sucrose, gelatin and hydroxypropylcellulose (pg. 27, lin. 23 – 37). The drug of the invention can be used in the treatment of various disorders ranging from cerebrovascular disease to renal disorders (pg. 23, lin. 24 – 44).

Wong shows the level of skill in the art that is known to combine tables delivering active agents comprising polyethylene and red ferric oxide (Examples).

Kawata, et al provides evidence to the level of skill in the art to combine and use such excipients in coated tablets similar to that of the invention. Fillers such as polyethylene glycol and citric acid (col. 1, lin. 44 – 65) are used in the tablet of the invention.

Regarding new claim 27, which recites a limitation drawn to the method for determining the percentage erosion, it is the position of the examiner that such a limitation does not impart patentability on the invention. The determination of an inherent property does not add new features or limitations to a previously disclosed product. Further the determination of

In view of the prior art one of ordinary skill in the art would have been motivated to combine the compressed coated tablet of Dandiker with the hydrogel-forming polymer of Nakashima. Dandiker suggests that the outer later of the compressed-coated tablet comprise

polyethylene glycol and other hydrogel-forming polymers. The coating of Nakashima comprises polyethylene glycol and other hydrogel forming polymers. The polymer is optimal for a timed-release delivery in the digestive tract, since the coating is formulated to allow the center to erode slowly as the unit passes over though the GI tract. A skilled artisan would have followed the suggestions of Dandiker to compression coat the tablet with a hydrogel-forming polymer and use the polymer of Nakashima to do so. A skilled artisan would have been motivated to combine the hydrophilic base/hydrogel-forming polymer preparation with the drug of Taniguchi in order to provide a sustained release profile for the drug to the lower intestinal tract. Following the knowledge on the art the skilled artisan could have substituted any number of excipients including those of Wong or Kawata into the preparation in order to add an aesthetic appeal or better erosion properties. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings and suggestion in this way, with an expected result of sustained release oral tablet capable of treating various renal and cardiovascular disorders.

Response to Arguments

7. Applicant's arguments filed 02/24/04 have been fully considered but they are not persuasive. Applicant argues that:

a. There is no motivation or suggestion to modify the references

8. Regarding this argument, it is the position of the examiner that sufficient motivation and suggestion exist in the combination of references to render the claims anticipated. To support this argument applicant commences in a piecemeal analysis of the references, pointing out the

deficiencies in each references, and ignoring critical disclosures. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Dandiker is relied upon for its disclosure of an erodible core comprising fillers, where the core is compression coated with hydrophilic polymers. Though lower viscosity polymers are preferred, Dandiker suggests that higher viscosity polymers would result in a more delayed release. A skilled artisan upon seeing this disclosure would be motivated to include higher viscosity polymers in order to further the release of the active agent. However, temporal limitations are not included in the instant claims. Applicant argues that the core of Dandiker does not erode between 40%-90%, yet it remains the position of the examiner that ***any*** tablet core would erode to this percentage given enough time in the GI tract. Since applicant provides no temporal (how fast the tablet erodes to this amount) or spatial (where this erosion occurs), information, the limitation cannot be given patentable weight. Dandiker is relied upon for its disclosure of its erodible core, and not solely for the anticipation of the invention. The reference is combined with Nakishima for it's disclosure of a hydrogel forming coating comprising high viscosity polyethylene oxides (examples), which allow for water to penetrate into the core, and erode it. Seeing the suggestion in Dandiker to include higher viscosity polymers to delay the release time, a skilled artisan would include the PEO of Nakashima into the coating, in order to deliver the active agent to specific areas of the GI tract. Applicant acknowledges that Nakishima discloses the use of sucrose as a filler in its invention,

which would be sufficient to provide a suggestion of similarity between the erodible cores of Dandiker, and Nakishima.

9. In response to applicant's argument that Wong provides no motivation to combine, the fact that applicant has recognized another advantage, which would flow naturally from following the suggestions of the prior art, cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Wong is used merely for its disclosure of red ferric oxide and polyethylene, showing that these components were known in the art as being capable of combination. Likewise for Kawata which discloses the use of citric acid as a filer. The commonality between these references is their reliance on polyethylene glycol as a component in the tablet. These references show the level of skill in the art regarding the particular minor components of the instant claims. Regarding Taniguchi, this reference discloses the specific fused benzazepine derivative as claimed by applicant. The reference suggests the inclusion of fillers and hydrophilic polymers.

10. It remains the position of the Examiner that given the combination of suggestions and teachings in the prior art obviate the claimed invention. A skilled artisan would follow the suggestions of Dandiker to include high viscosity hydrophilic polymers in order to provide a delayed release. Nakashima provides such high viscosity polymers that would allow for the targeted release of an active agent. Taniguchi provides the fused benzazepine useful in various vascular treatments. Wong merely provides an aesthetic appeal, which would be well within the level of skill in the art to modify with another colorant. Kawata provides fillers, which provides improved eroding properties, which would also be well within the level of skill in the art to include into the combination. This combination would be released in the lower GI tract due to

the polymers of Nakashima and be useful in the treatment of renal and cardiovascular disorders. For these reasons at least the claims remain obviated by the prior art.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

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